

06/19/03 THU 10:44 FAX 3015942077

FDA CDRH ODE POS

001



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

JUN 18 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Luis Arguello  
President  
DemeTECH Corporation  
12119 SW 131 Avenue  
Miami, Florida 33186

Re: K023030

Trade/Device Name: DemeTECH Polyester Nonabsorbable Suture  
Regulation Number: 21 CFR 878.5000  
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture  
Regulatory Class: II  
Product Code: GAT  
Dated: April 25, 2003  
Received: May 8, 2003

Dear Mr. Arguello:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

08/19/03 THU 10:44 FAX 3015942977

FDA CDRH ODE POS

002

Page 2 - Mr. Luis Arguello

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsamain.html>

Sincerely yours,

*Miriam C. Provost*  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**DEMETECH CORP**

K023030

**510 (k) Premarket Notification  
DemeTECH Polyester Nonabsorbable Suture**

**C. Indications for use of the Device**

Page 1 of 1

510(k) Number): Not known

Device Name: DemeTECH Polyester Nonabsorbable Suture

**Indications for Use:**

The DemeTECH Polyester Nonabsorbable Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular and ophthalmic and neurological procedures.

*(Please do not write below this line---continue on another page if needed)*

\* \* \* \* \*

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K023030

Prescription Use X or Over-the-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)